

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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IN RE ACTOS END-PAYOR ANTITRUST
LITIGATION

No. 13-CV-9244 (RA)
No. 15-CV-3278 (RA)

ORDER

IN RE ACTOS DIRECT PURCHASER
ANTITRUST LITIGATION

RONNIE ABRAMS, United States District Judge:

Defendants Takeda Pharmaceutical Company Limited, Takeda America Holdings, Inc., Takeda Pharmaceuticals U.S.A., Inc., and Takeda Development Center Americas, Inc. (collectively, “Takeda”) requests that this Court certify an interlocutory appeal, pursuant to 28 U.S.C. § 1292(b), of the September 30, 2019 Opinion and Order filed in *In re Actos End-Payor Antitrust Litigation*, No. 13-cv-9244, *see* Dkt. 272 (“EPP Order”), and the October 8, 2019 Opinion and Order filed in *In re Actos Direct Purchaser Antitrust Litigation*, No. 15-cv-3278, *see* Dkt. 131 (“DPP Order,” and, collectively with the EPP Order, the “Orders”). For the reasons that follow, the Court certifies the Orders for interlocutory appeal.

BACKGROUND

The Court assumes familiarity with the underlying facts and procedural history of these two related cases, which are described at length in the Orders. *See In re Actos End-Payor Antitrust Litig.*, No. 13-CV-9244 (RA), 2019 WL 4805843 (S.D.N.Y. Sept. 30, 2019); *In re Actos Direct Purchaser Antitrust Litig.*, No. 15-CV-3278, 2019 WL 5011456 (S.D.N.Y. Oct. 8, 2019). Takeda filed its motion to certify an interlocutory appeal under Section 1292(b) in both cases on November 22, 2019. *See* No. 13-cv-9244, Dkt. 294; No. 15-cv-3278, Dkt. 161. The indirect purchasers (“End-Payor Plaintiffs” or “EPPs”) and the direct purchasers (“Direct-Purchaser Plaintiffs” or “DPPs”) together filed an opposition on December 13, 2019, *see* No. 13-cv-9244, Dkt. 304; No. 15-cv-3278, Dkt. 178, and Takeda filed its reply on December 24, 2019, *see* No. 13-cv-9244, Dkt. 306; No. 15-cv-3278, Dkt. 182.

DISCUSSION

Section 1292(b) presents a limited exception to the “basic tenet of federal law” that appellate review should be delayed until final judgment is entered. *Koehler v. Bank of Bermuda Ltd.*, 101 F.3d 863, 865 (2d Cir. 1996) (citing *Coopers & Lybrand v. Livesay*, 437 U.S. 463, 475 (1978)). Pursuant to this provision, a district court may certify for appeal an otherwise non-appellable order when the court concludes: “(1) that such order involves a controlling question of law (2) as to which there is a substantial ground for difference of opinion and (3) that an immediate appeal from [that] order may materially advance the ultimate termination of the litigation.” *In re Facebook Inc., IPO Sec. & Derivative Litig.*, 986 F. Supp. 2d 524, 529 (S.D.N.Y. 2014) (quoting 28 U.S.C. § 1292(b)). “Section 1292(b)’s legislative history reveals that although that law was designed as a means to make an interlocutory appeal available, it is a rare exception to the final judgment rule that generally prohibits piecemeal appeals. The use of § 1292(b) is reserved for

those cases where an intermediate appeal may avoid protracted litigation.” *Koehler*, 101 F.3d at 865-66 (citation omitted). Accordingly, “only ‘exceptional circumstances [will] justify a departure from the basic policy of postponing appellate review until after the entry of a final judgment.’” *Klinghoffer v. S.N.C. Achille Lauro Ed Altri-Gestione Motonave Achille Lauro in Amministrazione Straordinaria*, 921 F.2d 21, 25 (2d Cir. 1990) (quoting *Coopers & Lybrand*, 437 U.S. at 475). Such circumstances are present here.

In the Orders, the Court denied Takeda’s motion to dismiss the monopolization claims asserted against it, holding that the plaintiffs had plausibly alleged that Takeda engaged in anticompetitive behavior by falsely representing to the FDA that its ’584 and ’404 patents in connection with the ACTOS NDA (the “Patents”) were accurately described in the Orange Book as drug product patents for the ACTOS NDA. *See* EPP Order at 25-26; DPP Order at 12-13.¹ Takeda now seeks an interlocutory appeal with respect to the Court’s interpretation of Section 355(b)(1)—and, in particular, the meaning of the word “claims” in that provision. Although the Court remains of the view that the plain meaning of “claims” in Section 355(b)(1) applies in the phrase “claims the drug,” while the infringement meaning of “claims” applies in the phrase “claims a method of using such drug,” EPP Order at 25-26, the Court nevertheless concludes that Takeda has made the requisite showing to certify the Orders for interlocutory appeal.

First, both Orders involve a controlling question of law. For purposes of an interlocutory appeal, the “‘question of law’ must refer to a ‘pure’ question of law that the reviewing court could decide quickly and cleanly without having to study the record.” *Capitol Records, LLC v. Vimeo*,

¹ The bulk of the Court’s reasoning, as relevant to the instant motion, is contained in the EPP Order. *See* EPP Order at 10-26. In the DPP Order, the Court denied Takeda’s motion for the same reasons articulated in the EPP Order, recognizing that the DPPs’ “monopolization claim against Takeda, based on Takeda’s allegedly improper Orange Book listings, is essentially identical to that asserted by the EPPs,” as was “Takeda’s motion to dismiss that claim in these two related actions.” *See* DPP Order at 12.

LLC, 972 F. Supp. 2d 537, 551 (S.D.N.Y. 2013) (citation omitted). It must also be “controlling,” such that “reversal of the district court’s order would terminate the action,” *Klinghoffer*, 921 F.2d at 24, or “at a minimum that determination of the issue on appeal would materially affect the litigation’s outcome,” *Capitol Records*, 972 F. Supp. 2d at 551 (citation omitted). The issue here is one of statutory interpretation—in particular, the meaning of the word “claims” in Section 355(b)(1)—which “the reviewing court could decide quickly and cleanly without having to study the record.” *Capitol Records*, 972 F. Supp. 2d at 551. Moreover, if the Court of Appeals were to interpret Section 355(b)(1) in accordance with the construction advanced by Takeda, that conclusion would put an end to the instant litigation. Accordingly, the first statutory factor has been met.

Second, although the Court’s reading of the word “claims” in Section 355(b)(1) remains unchanged, it recognizes that there exists a substantial ground for difference of opinion on this issue. The “substantial ground for a difference of opinion” requirement is met where “(1) there is conflicting authority on the issue, or (2) the issue is particularly difficult and of first impression for the Second Circuit.” *In re Enron Corp.*, No. 06 Civ. 7828 (SAS), 2007 WL 2780394, at *1 (S.D.N.Y. Sept. 24, 2007) (citation omitted). It is true that “the mere presence of a disputed issue that is a question of first impression, standing alone, is insufficient to demonstrate a substantial ground for difference of opinion.” *In re Flor*, 79 F.3d 281, 284 (2d Cir. 1996). Rather, the court must “analyze the strength of the arguments in opposition to the challenged ruling when deciding whether the issue for appeal is truly one on which there is a *substantial* ground for dispute.” *Id.* (citation omitted). Here, the Court specifically acknowledged that both parties made strong arguments in support of their differing interpretations, but nonetheless concluded that neither party’s construction was entirely accurate. *See* EPP Order at 12. Given the absence of controlling

authority, as well as the novelty and complexity of the issue, the Court is persuaded that substantial ground for difference of opinion exists as to the meaning of the word “claims” in Section 355(b)(1). Furthermore, as the Court noted in the EPP Order, this issue is a question of first impression, *see* EPP Order at 12, and may have important ramifications for other companies in the pharmaceutical industry. *See Transp. Workers Union of Am. v. N.Y.C. Transit. Auth.*, 358 F. Supp. 2d 347, 353 (S.D.N.Y. 2005) (noting that certification of an interlocutory appeal was appropriate where the case “raise[d] a novel issue of great importance to many [others in the industry]” and the case “may therefore have considerable precedential value”). The second statutory factor is thus satisfied.

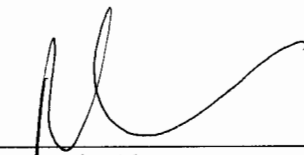
Finally, an intermediate appeal would materially advance the ultimate termination of this litigation. Courts “place particular weight” on this third factor, which is “closely connected” to the first factor. *See Capitol Records*, 972 F. Supp. 2d at 551 (citations omitted); *see also In re Enron*, 2007 WL 2780394, at *2 (“[A]n immediate appeal is considered to advance the ultimate termination of the litigation if that appeal promises to advance the time for trial or shorten the time required for trial.”) (citation omitted). If the Court of Appeals were to adopt Takeda’s interpretation of Section 355(b)(1), Takeda’s motions to dismiss would be granted, and the litigation would end. As Takeda points out, such an outcome would “avoid the significant expense and burdens attendant to this type of complex, class action litigation.” Takeda Mot. at 14. Moreover, any “risk of short-term delay” of the resolution of this case by certifying an interlocutory appeal is “outweighed by the potential advantage of materially advancing the *ultimate termination* of the litigation.” *See In re Trace Int’l Holdings, Inc.*, No. 04 Civ. 1295 (KMW), 2009 WL 3398515, at *3 (S.D.N.Y. Oct. 21, 2009).

CONCLUSION

For the foregoing reasons, Takeda's motion to certify for interlocutory appeal the EPP and DPP Orders is granted, and Takeda's request for oral argument is denied as moot. The Clerk of Court is respectfully directed to terminate the motions at Dkts. 294 and 307 in the case number 13-cv-9244 and the motions at Dkts. 161 and 184 in the case number 15-cv-3278.

SO ORDERED.

Dated: January 28, 2020
New York, New York

A handwritten signature in black ink, consisting of a stylized 'R' followed by a series of loops and a long horizontal stroke.

Ronnie Abrams
United States District Judge